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SEP 26 2011

Traditional 510(k) Summary

A) SUBMITTED BY : Kepler MedTec
223 Avenue D
Willston, VT 05495
Registration # 3008160705

CONTACT: Sharyn Orton, PhD
MEDIcept Inc.
200 Homer Ave
Ashland, MA 01721
401-330-8264
508-231-8861 Fax

B) DEVICE NAME: Disposable Bipolar Cable

COMMON NAME: Disposable Bipolar Cable

DEVICE CLASS: 21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories, Class II

PRODUCT CODE: GEI

C) PREDICATES:

- K970993 DeRoyal Industries, Inc. - Disposable Bipolar Electrosurgical Cable

D) DEVICE DESCRIPTION:

The Kepler MedTec Disposable Bipolar Cable includes four cables available in multiple colors. The Kepler MedTec Disposable Bipolar Cable is provided sterile.

Bipolar forceps (handpiece) are connected to a generator through a bipolar cable. The bipolar cable is flexible and delivers the electrical power from the generator to the bipolar forcep. There is a male and female end termination on the cable. The male end termination (2-pin banana connector) is connected to the generator; the female end termination (2-pin plug type connector) to the bipolar forceps.

The Kepler MedTec Disposable Bipolar Cable is compatible with:

- Bipolar Forceps using standard US connection with 5.8 mm spaced pins
- VallyLab, Conmed, Medtronic and Bovie generators

E) INTENDED USE: The Kepler MedTec Disposable Bipolar Cable is intended to connect an electrosurgical device to an electrosurgical generator. It is indicated for use with bipolar forceps during general surgical procedures.

F) SUBSTANTIAL EQUIVALENCE COMPARISON AND DISCUSSION

Device Features	**Kepler MedTec Disposable Bipolar Cables**	DeRoyal Disposable Bipolar cables
	TBD	K970993
Intended Use/Indication for Use	Are intended to connect an electrosurgical device to an electrosurgical generator. Indicated for use with bipolar forceps during general surgical procedures.	Indicated for use during electrosurgical procedures to provide transmission of electrical power from a electrosurgical generator to a bipolar instrument
Patient Usage	Single use disposable provided sterile	Single use disposable provided sterile
Cable length	3660 mm	366 cm
Electrical safety/EMC	IEC 60601-2-2 compliant	IEC 60601-2-2 compliant

The Kepler MedTec Disposable Bipolar Cable has the same intended use, target population, clinical setting, and technology as the predicate device. Kepler MedTec believes that the differences between Kepler MedTec Disposable Bipolar Cable and the predicate (i.e. cable color, materials, any slight differences in dimensions; reusability) does not raise new issues of safety or effectiveness.

G) CONCLUSION

The Kepler MedTec Disposable Bipolar Cable has the same intended use, target population, clinical setting, and technology as the predicate devices. Kepler MedTec believes the Kepler MedTec Disposable Bipolar Cable is therefore substantially equivalent to the predicate devices based on intended usage, technology comparison and system performance.

H) TESTING

No clinical testing was submitted with this application.

I) OTHER

The Kepler MedTec Disposable Cable is:

- Compliant with IEC 60601-2-2 (2006): *Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment*
- For EtO sterilization, compliant with ANSI/AAMI 10993-7; ISO 11135-1; ISO 11137-1; ISO 11138-1
- Biocompatible

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 26 2011

Kepler MedTec
% MEDIcept, Inc.
Sharyn Orton, Ph.D.
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K110462
Trade/Device Name: Kepler MedTec Disposable Bipolar Cable
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 06, 2011
Received: September 08, 2011

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin M. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110462

Indications for Use Form

510(k) Number (if known):

Device Name: Disposable Bipolar Cable

Indications for Use: The Kepler MedTec Disposable Bipolar Cables are intended to connect an electrosurgical device to an electrosurgical generator. They are indicated for use with bipolar forceps during general surgical procedures.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110462